

of profound mitral regurgitation that may not be adequately addressed by the subsequent valve replacement. The lack of an effective mitral valve may lead to overwhelming hemodynamic instability that may not be tolerated by the already compromised left ventricle and overwhelming pulmonary edema may rapidly result.

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### **Object of the Invention**

It is the object of the present invention to overcome or substantially ameliorate at least one of the above disadvantages.

### **Summary of the Invention**

There is disclosed herein a percutaneous heart valve prosthesis comprising:  
10 a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending  
15 across said passage for blocking bloodflow in one direction through said passage;

an anchor frame formed of elongate elastic anchor frame elements, said anchor frame being collapsible from a stable substantially flat disc-like configuration to an unstable elongate configuration for location within a catheter; and

a flexible anchor line secured to and extending between said valve body and said  
20 anchor device.

The anchor frame elements may each be formed of a superelastic shape memory material.

The valve body may comprise a collapsible valve body frame formed of elongate elastic valve body elements. The valve body frame elements may each be formed of a  
25 superelastic shape memory material.

The valve body typically tapers toward said valve body first end. The anchor line is then usually secured to said valve body first end.

The valve body frame may comprise at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said  
30 deltoid having acute-angled vertices at said valve body first and second ends, and

oblique-angled vertices located between said valve body first and second ends. Each valve body sub-frame member may have the general form of a rhombus.

The valve body sub-frame members may be joined at respective said oblique-angled vertices.

5 Each sub-frame member may further comprise a collapsible diagonal element extending between said oblique-angled vertices. The one or more valve elements is/are generally secured to the diagonal elements.

The valve body frame may alternatively be in the general form of a collapsible cylindrical ring.

10 The prosthesis may further comprise a plurality of prongs spaced about a periphery of said valve body for engaging the native wall of a valve orifice in use.

The prosthesis may still further comprise a flexible skirt extending about a periphery of said valve body for blocking blood flow in said one direction between said valve body and the native wall of a valve orifice in use. Said flexible skirt may be formed  
15 of biological material, typically pericardial material.

The prosthesis is typically a mitral valve prosthesis.

There is further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;  
20 a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end, said anchor device being in a collapsed state and located between said valve body and said catheter second end; and  
an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said anchor device  
25 and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;  
30 creating a puncture in the inter-atrial septum of the heart;  
advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined above in said catheter with said valve body and said anchor device in a collapsed state, said valve body being located between said anchor device and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released  
5 from said catheter first end, thereby expanding said valve body from said collapsed state;  
withdrawing said catheter first end through the mitral valve into the left atrium;  
withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve;

withdrawing said catheter first end through said puncture and into said right atrium;  
10 advancing said anchor device through said catheter until said anchor device is released from said catheter first end, thereby expanding said anchor device from said collapsed state;

engaging said anchor device with said inter-atrial septum about said puncture; and  
withdrawing said catheter from the patient.

15 There is yet further disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve being collapsible about said longitudinal axis for delivery via  
20 catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

wherein said valve body tapers linearly from said valve body second end to said valve body first end, said valve body first end being sized to pass through a valve orifice  
25 associated with a heart valve to be replaced, said valve body second end being sized so as not to pass through the valve orifice.

The valve body may comprise a collapsible valve body frame formed of elongate elastic valve body elements. The valve body frame elements may each be formed of a superelastic shape memory material.

30 The valve body frame may comprise at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and oblique-angled vertices located between said valve body first and second ends. Each valve body sub-frame member may have the general form of a rhombus.

The valve body sub-frame members may be joined at respective said oblique-angled vertices.

Each sub-frame member may further comprise a collapsible diagonal element extending between said oblique-angled vertices. The one or more valve elements is/are  
5 generally secured to said diagonal elements.

The prosthesis is typically a mitral valve prosthesis.

The prosthesis may further comprise a plurality of prongs spaced about a periphery of said valve body second end.

There is yet further disclosed herein a percutaneous heart valve replacement system  
10 comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element  
15 second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing heart valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be  
20 treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined above in said catheter with said valve body in a  
25 collapsed state and said valve body second end located between said valve body first end and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

30 withdrawing said valve body toward the left atrium, wedging said valve body in the orifice of the native mitral valve; and

withdrawing said catheter from the patient.

There is further disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage  
35 extending along a longitudinal axis between said valve body first end and said valve body

second end, said valve being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage; and

5 a plurality of prongs spaced about a periphery of said valve body second end;

wherein said valve body tapers toward said valve body first end, said valve body first end being sized to pass through a valve orifice associated with a heart valve to be replaced, said valve body second end being sized so as not to pass through the valve orifice.

10 There is further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

15 an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing mitral valve comprising the steps of:

20 advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

25 locating a prosthesis as defined above in said catheter with said valve body in a collapsed state and said valve body second end located between said valve body first end and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

30 withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, wedging said valve body in the orifice of the native mitral valve and engaging said prongs with cardiac structure surrounding an end of said orifice; and

withdrawing said catheter from the patient.

6a

There is still further disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

a flexible skirt extending about a periphery of said valve body for blocking bloodflow in said one direction between said valve body and the native wall of a valve orifice in use.

The flexible skirt may be formed of biological material, typically pericardial material.

The prosthesis is typically a mitral valve prosthesis.

There is still further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

6b

locating a prosthesis as defined above in said catheter with said valve body in a collapsed state;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

5 withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve with said skirt located toward the left ventricle; and

withdrawing said catheter from the patient.